## Op-Ed

## The cost to global health of drug company profits

These profits are made on the losses of vulnerable people

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West J Med 2001;174:302-303 A profit basely made is the same as a loss.

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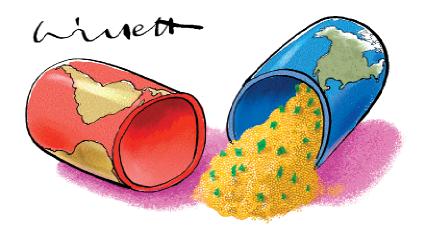
There is nothing inherently wrong with a company making a profit. Indeed, profit can be "an enabler because it takes people and peoples beyond subsistence levels to the amenities of life, to comfort and culture, to new knowledge and new possibilities." The problem comes when profits are made out of other people's losses. The US pharmaceutical industry is immensely profitable, enjoying a current rate of return on investment that is over twice the US average.² But these profits come at great expense to people in the developing world. The poorest of countries are losing out in at least 3 ways.

First, drug companies are increasingly testing their new products on people who will never benefit from them. Evidence exists that companies see the developing world as a "virgin territory" with millions of potential trial subjects. For example, CenterWatch, a clinical trials listing service, recently published an article called "Latin American fever," in which it said that the continent "may offer a unique opportunity to reach much larger numbers of study subjects."3 In 1994, Eli Lilly enrolled just 590 trial patients across Africa, the Middle East, and central and eastern Europe. This year, the company expects to enroll 7,309 subjects.<sup>4</sup> It is cheaper to conduct trials in poor countries, which often have fewer regulatory controls, so the industry stands to benefit. But the trial subjects rarely do. Trials in poor countries are associated with local improvements in health care only while the trials are ongoing. The improvements are rarely sustained after the trials end and the companies have withdrawn their treatments and patient monitoring.<sup>5</sup> Many drugs tested in the developing world are designed to treat conditions that largely affect industrialized, not developing, nations. And although in theory new treatments may be available to all who might benefit after being tested in poor countries, their inflated prices usually put them out of the reach of the study population.

The second way in which the poor lose out is that drug companies can refuse to market products that would save lives in the tropics but do not reap corporate rewards. An illustration is the story of the drug eflornithine, which was originally developed—but found to be ineffective—as an anticancer agent. The drug is effective against African sleeping sickness,<sup>6</sup> which claims thousands of lives annually in sub-Saharan Africa. It is the only known treatment for the resistant form of the disease, which has a prevalence of up to 20% in parts of Uganda.7 Hoechst Marion Roussel, the company that developed it, stopped its production in 1999, citing commercial failure. This decision left thousands dying of a curable illness without treatment. Would the US government stand by and allow a drug company to refuse to market a safe treatment for a disease that killed thousands of US citizens every year? We doubt it. And there is a distasteful twist in the story. Bristol-Myers Squibb and Gillette have just introduced Vaniga, a facial cream containing eflornithine HCl, the "first and only prescription cream proven to slow the growth of unwanted facial hair in women" (www.vaniga.com). The drug may indeed reach Africa, but only because its cosmetic properties make it profitable.

A third way in which the pharmaceutical industry stands to profit at the expense of others is in its attempts to prevent poor countries from manufacturing generic versions of essential medicines. The industry fiercely guards its patents, and it has been aided by the World Trade Organization's agreements on intellectual property rights, which include the right to exclusively market a patented drug for at least 20 years. The agreements do allow poor countries to produce their own generic drugs during public health crises. When countries have attempted to do so, however, the US government, lobbied by the pharmaceutical industry, has often threatened them with trade sanctions.

The Pharmaceutical Research and Manufacturers Association, a US pressure group, urges US trade action against poor countries, such as India and Egypt, for pro-



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ducing generic drugs (see www.phrma.org). In Brazil, local companies have been able to manufacture human immunodeficiency virus (HIV) drugs at lower cost, allowing the Brazilian government to distribute the drugs freely to HIV-infected patients. But the program is in jeopardy because the US government has initiated legal proceedings against Brazil, at the instigation of the US drug giants. 10 While former president Clinton promised to stop pressuring poor countries that wish to produce their own essential drugs, 11 President Bush has offered no such concessions. Instead, many observers think that his government will "return to its customary role as a battering ram for the interests of the pharmaceutical industry."2 It is no wonder that the industry spent nearly 70% of its \$24.4 million election campaign war chest on backing the Republican party.2

The pharmaceutical industry's continued free reign in an unfettered free market is unacceptable. New, robust ethical standards for clinical trials should be enforced by recognized and respected organizations, with tough financial penalties imposed on companies who flout them. In particular, the industry must heed the newly revised Declaration of Helsinki, which states that "medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research." The industry must take more responsibility for improving access to medicines in the developing world. It must invest some of its huge profits in marketing drugs aimed specifically at

tropical diseases, cut drug costs immediately in poor countries, and put an end to its patent claims in these regions. The only freedom that the free market is currently offering to those in poor countries is the freedom to die without treatment.

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